UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,380	03/29/2004	Iftikhar Khan	1800-000001	2606

27572 7590 06/16/2008

HARNESS, DICKEY & PIERCE, P.L.C.
P.O. BOX 828
BLOOMFIELD HILLS, MI 48303

EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
06/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,380	KHAN ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the graded inside diameter of the cuff as set forth in claims 1, 13, and 17 must be shown or the feature(s) canceled from the claim(s). Applicant illustrates and argues that the venous outflow catheter 12 is 1mm smaller in diameter than the PTFE graft 11. However, applicant has not specifically illustrated the *graded inside diameter of the cuff* to show that it accommodates the varying diameters of the tubes. A "graded" surface indicates a sloping surface, which applicant has not illustrated commensurate in scope with the claims. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-5, 7-10, 12-14, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al.

In the specification and figures, Squitieri discloses the device substantially as claimed by applicant. With regard to claim 1, Squitieri discloses an arteriovenous shunt system comprising an arterial graft 53 with a lead end 62 anastomosed to an artery and terminal end connected to needle access site 80, which acts as a connector that corresponds to applicant's cuff. The system further comprises a venous outflow catheter 65 with an outflow end that is capable of being inserted through a vein at 40 into the right atrium of the heart (see FIGS 6-9) and an inflow end that is connected to connector 80 (see column 4). The access site 80, corresponding to applicant's cuff, directs passage of blood from the arterial catheter to the venous catheter, and is in communication with the terminal end of the arterial graft and the inlet end of the venous catheter (see FIGS 6-9, column 5, lines 19-60). Squitieri further discloses that the

arterial and venous catheters may be connected in various manners by cuffs that may comprise a cylindrical shape (see FIGS 2, 4, 6, 9, 11, 12, 14).

With regard to applicant's recitation of the diameters of the arterial and venous catheters in claims 1, 4, 5, 8, 9, 12, 14, and 18, Squitieri discloses that the shunt may be manufactured in a variety of different linear lengths and interior and exterior diameter sizes (see column 3, line 60 to column 4, line 15). It has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP 2144.04(IV)(A). It appears that the device and method disclosed by Squitieri would perform in the same manner as claimed by applicant. Therefore, the sizes claimed by applicant are held by the examiner to be an obvious variation of the device and method disclosed by Squitieri.

Squitieri fails to disclose that the cuff or connector comprises a graded inside diameter to accommodate the various catheter diameters. However, such connectors that accommodate various diameter conduits are well known in the art of fluid handling, as demonstrated by Parks. Parks discloses a medical fluid handling apparatus with a ferrule or connector 70 that receives and joins different sized conduits with graded interior wall regions 82, 84, 86 (see FIG 7, column 4, lines 55-62). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a graded interior surface as disclosed by Parks to the connector between the arterial and

venous catheters in the vascular access system disclosed by Squitieri in order to accommodate inserts of various diameters, as taught by Parks.

With regard to claims 2, 3, and 7, Squitieri discloses that in an embodiment, tubing or cuff 69 is made of PTFE (polytetrafluoroethylene), a biocompatible, flexible material (see FIG 8, column 5, lines 55-60).

With regard to claim 13, Squitieri discloses that the arteriovenous graft system may be connected to a hemodialysis machine (not shown), meeting the limitations of the claim (see column 4, lines 60-64).

4. Claims 6, 11, 15, 16, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al, further in view of US 5,591,226 to Trerotola et al.

In the specification and figures, Squitieri and Parks disclose the device and method substantially as claimed by applicant (see rejection above) with the exception of the particular arteries and veins that are used to connect to the arteriovenous system. Squitieri is silent as to the particular vessels used, but it is well-known in the art of arteriovenous grafts that one may select any given vessel based on the suitability for its purpose. Trerotola discloses a stent-graft that may be deployed between many vessels within a patient, and discloses a graft between a brachial artery and an axillary vein (see FIG 9A and accompanying text). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to connect the arteriovenous graft system

disclosed by Squitieri to the brachial artery and axillary vein as disclosed by Trerotola in order to create blood flow between the selected vessels, as demonstrated by Trerotola.

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,591,226 to Trerotola et al.

In the specification and figures, Squitieri and Parks disclose the device and method substantially as claimed by applicant (see rejection above) with the exception of using polyurethane as a catheter material. Trerotola discloses a stent-graft that may use polyurethane as a biostable flexible material (see column 2, lines 25-33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use polyurethane as disclosed by Trerotola in the catheter suggested by the cited prior art, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

6. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al, further in view of US 5,509,897 to Twardowski et al.

With regard to claim 17, the cited prior art discloses the method substantially as claimed by applicant (see rejection above). In particular, Squitieri discloses that the graft may be surgically inserted (see column 7, lines 24-45), connected to a hemodialysis machine (which, by definition, purifies blood), collect blood through the arterial catheter, send the blood through a dialysis machine, and collect blood from the dialysis machine

and return it to the patient via the venous catheter (see column 4, lines 50-64). Squitieri fails to disclose that the treated blood is deposited directly into the right atrium, but suggests such an arrangement in the illustrations of FIGS 7 and 9, which show venous catheter 65 extending towards the heart via vena cava 40. Blood flows from the vena cava into the right atrium. Nonetheless, Twardowski discloses an apparatus and method for hemodialysis in which a venous catheter comprises a distal end 138a disposed within the right atrium, delivering treated blood to the right atrium in order to provide a long-term indwelling catheter (see FIG 9 and accompanying text, column 6, lines 15-48, column 11, lines 15-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to advance the catheter disclosed by the cited prior art deeper into the patient's vasculature to the right atrium, as disclosed by Twardowski, in order to provide a long-term indwelling catheter without major drawbacks, as taught by Twardowski.

Response to Arguments

7. Applicant's amendment and arguments and filed 28 April 2008 have been fully considered but they are not persuasive.

8. Applicant argues that the connector 20/80 (see Squitieri FIG 9) disclosed by Squitieri is not the same as the cuff claimed by applicant. The connector disclosed by Squitieri connects the arterial inflow graft to the venous outflow catheter as claimed by applicant. Squitieri does not specifically define a graded interior, but the Examiner has relied upon the Parks reference to teach a graded interior to provide a secure fit

between catheters of different sizes. Accordingly, the instantly claimed apparatus is suggested by the cited prior art.

9. Applicant argues that Squitieri does not disclose that the venous outflow catheter is passed into the right atrium. However, Squitieri illustrates that the catheter is placed in what a person of ordinary skill in the art would recognize as the jugular vein, tunneled to what one of ordinary skill in the art would recognize as the vena cava and to the right atrium (see Squitieri FIG 9). As such, the Squitieri apparatus is "configured to," or of an appropriate size and shape to be deployed in the location claimed by applicant. Applicant argues that it is unreasonable to suggest that Squitieri's catheter can be advanced to the right atrium because the reference does not mention the names of the veins in which the apparatus is deployed. However, an analysis of obvious "need not seek out precise teachings directed to the specific subject matter of the challenged claim." *KSR v. Teleflex Inc.* 127 S.Ct. 1727, 1741 (2007). The fact-finder may take account of the inferences and creative steps that a person of ordinary skill in the art would employ. *Id.* As such, it is not necessary that Squitieri name the veins in which the venous return catheter is placed, especially since the reference illustrates that the catheter is placed in what one of ordinary skill in the art would recognize as the jugular, vein, extending into the vena cava towards the right atrium. Accordingly, the instantly claimed apparatus is unpatentable over the disclosures of Squitieri and Parks.

10. Applicant argues that the device and method disclosed by Squitieri performs differently than that claimed by the applicant. However, the Applicant has failed to provide any objective evidence that suggests that the two devices function differently.

The apparatus claimed by applicant has the same structural features as that disclosed by Squitieri and Parks. There is no claimed structural feature nor evidence that that the instantly claimed invention functions any differently than the invention disclosed by the prior art. Accordingly, the instantly claimed invention is unpatentable over the cited prior art.

11. In response to applicant's argument that Parks is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the Examiner relies on the Parks reference to teach a connector that connects two fluid conduits, which is analogous to both the concept of fluid transfer in Squitieri and applicant's invention. One of ordinary skill in the art would be motivated to look to connectors in fluid transfer devices to provide a connector for the fluid transfer device disclosed by Applicant.

12. Applicant argues that PTFE grafts are known in the art of arteriovenous grafts and cannot be the basis of any rejection. The Examiner notes that the concept of patentability is based on novelty or non-obviousness. (See 35 USC §§102, 103.) If a particular material is known to be used in the art, the use of that particular material by Applicant is neither novel nor non-obvious. Accordingly, the basis for the rejection is sound.

13. Applicant argues that the components for hemodialysis as recited in claim 13 are known in the art, and the application of such components known in the art against the instant invention renders them "invalid." When an Examiner cites prior art references against an instantly claimed invention, the citation does not invalidate the prior art references. The references are used to show that the elements are known in the art and cannot, therefore, be claimed by applicant to be novel and nonobvious components of an invention.

14. Applicant argues that "Squitieri cannot be the only claimant of the arteriovenous shunt method for dialysis." It is unclear what applicant means by this statement. The Examiner asserts that Squitieri discloses an apparatus that renders obvious the invention *claimed* by applicant. She does not assert that Squitieri maintains the only method of dialysis by arteriovenous shunting.

15. With regard to claim 17, the Examiner has amended her rejection to add a reference suggesting the location of blood return in the right atrium, as presented in the amended claim.

16. Applicant argues that the Trerotola reference is inserted in a manner different than that claimed by applicant and cannot be used as a basis for rejection. However, the Examiner is not relying on the Trerotola reference to teach a method of insertion. Examiner relies on Trerotola to show that it is known in the art to deploy stent grafts between the vessels claimed by applicant, rendering the method claimed by applicant neither novel nor non-obvious. Accordingly, the claims are properly rejected under the combined cited art.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
10 June 2008